

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in December 2009.

---

### Original Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 141-297

Trade Name: Prozinc®  
Ingredients: Protamine zinc recombinant human insulin  
Sponsor: Boehringer Ingelheim Vetmedica, Inc.  
Approval Date: October 28, 2009  
Status: OTC  
Route: Subcutaneous  
Species: Cats  
Drug Form: Injectable aqueous suspension  
Concentration: 40 international units (IU) insulin/mL  
Indications: For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.  
Exclusivity: Under section 106 of the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670), Prozinc® is not eligible for generic copying because it is a drug primarily manufactured using biotechnology.

21 CFR 522.1160 74 FR 66047

---

### Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 141-265

Trade Name: NuflorGOLD™  
Ingredients: Florfenicol  
Sponsor: Intervet, Inc.  
Approval Date: September 4, 2009

This supplement provides adding *Mycoplasma bovis* to the list of the list of target pathogens for the BRD treatment indication.

21 CFR 522.955 74 FR 66573

#### NADA Number: 141-172

Trade Name: Paylean® and Tylan®  
Ingredients: ractopamine hydrochloride, tylosin phosphate  
Sponsor: Elanco Animal Health, a Div. of Eli Lilly & Co.  
Approval Date: October 23, 2009

This supplement provides use of two-way combination Type B and C medicated swine feeds formulated with ractopamine hydrochloride and tylosin phosphate following use of tylosin tartrate medicated drinking water consistent with the sequential use approved for single-ingredient tylosin medicated swine feed (73 FR 76946, December 18, 2008).

21 CFR 558.500 74 FR 66914

## **Actions Taken by FDA Center for Veterinary Medicine**

The following corrections or additions to the list were published in the Federal Register in December 2009.

### **NADA Number: 140-901**

Trade Name: Adequan® i.m. Multi-Dose  
Ingredients: Polysulfated glycosaminoglycan  
Sponsor: Luitpold Pharmaceuticals, Inc.  
Approval Date: November 10, 2009

This supplement provides for the addition of 20, 30, and 50 mL multiple-dose vials.

*21 CFR 522.1850 74 FR 67816*

---

### **Sponsor Change**

---

### **NADA Numbers: 115-732**

Previous: Schering-Plough Animal Health Corp.

New Sponsor: Janssen Pharmaceutica NV.

Drug Labeler Code: 012578

*21 CFR 522.15, 510.600(c), 74 FR 65689*

**NADA Numbers: 034-478, 034-621, 045-188, 102-380, 104-494, 111-278, 120-648, 121-473, 128-620, 131-310, 131-675, 132-872, 137-600, 138-612, 139-189, 140-856, 140-897, 140-927, 140-954, 140-992, 141-222, 141-236, 141-258, 141-269, 141-276, 141-278, 141-280, 141-282, 141-286 and**

**ANADA Numbers: 200-134 and 200-239**

Previous: Schering-Plough Animal Health Corp.

New Sponsor: Intervet, Inc.

Drug Labeler Code: 000061

*21 CFR 510.600(c), 74 FR 66047*

### **ANADA Number: 200-257**

Previous: Bioniche Animal Health USA, Inc.

New Sponsor: Bioniche Teoranta

Drug Labeler Code: 063286

*21 CFR 522.1222a, 510.600(c), 74 FR 66573*

### **ANADA Number: 200-237**

Previous: Nicholas Piramal India Ltd.

New Sponsor: Piramal Healthcare Ltd.

Drug Labeler Code: 065085

*21 CFR 529.1186, 510.600(c), 74 FR 68529*